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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/714,712	11/15/2000	Juergen Schmitz	830003-2002.1	4820
7590	10/21/2003		EXAMINER	
EWOLDT, GERALD R				
ART UNIT			PAPER NUMBER	
1644				

DATE MAILED: 10/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/714,712

Applicant(s)

SCHMITZ ET AL.

Examiner

G. R. Ewoldt, Ph.D.

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11/20/02, 3/13/03, 7/21/03, 7/23/03.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 155-179 is/are pending in the application.
- 4a) Of the above claim(s) 168 and 172-178 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 155-167, 169-171 and 179 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) NA.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

1. Applicant's election of Group I, and the antigen binding fragment species AC144, filed 3/13/03, with traverse, is acknowledged. Applicant traverses the restriction requirement on the grounds that the examination of Groups I and II together would not pose a serious burden.

Upon reconsideration, Groups I and II are rejoined.

The restriction requirement is still deemed proper and is therefore made FINAL.

2. Claims 168 and 172-178 are withdrawn from further consideration by the Examiner, under 37 C.F.R. § 1.142(b) as being drawn to non-elected inventions.

Claims 155-167, 169-171, and 179 are being acted upon.

3. Applicant is advised that due to the Office's new electronic application format the Examiner no longer has access to the actual specification and can no longer make informal changes such as updating priority data or correcting minor errors such as mistakes in spelling. Applicant is advised that spelling errors have been noted in the specification. All such changes must now be made by formal amendment.

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claim 160 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

It is apparent that the antibodies AC144, AD5-13A11, and AD5-4B8 are required to practice the claimed invention. As required elements, they must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. A deposit may be made under the provisions of the

Budapest Treaty; an affidavit or declaration to that effect is required. See 37 CFR 1.801-1.809.

In addition to the conditions under the Budapest Treaty, Applicant is required to satisfy that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a U.S. patent.

Applicant's deposit and provision of these assurances through the submission of an appropriate declaration would obviate this rejection.

6. Claims 155-167, 169-171, and 179 are rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. This is a new matter rejection.

The specification and the claims as originally filed do not provide support for the invention as now claimed, specifically, the recitation of:

A) "An isolated antigen-binding fragment ... wherein said BDCA-2 protein is encoded by exons 1-6; exons 1 and 3-6; exons 1-2 and 4-6; or exons 1-3 and 5-6 of SEQ ID NO:1", (Claim 155).

B) "The antigen-binding fragment of claim 156 wherein the antibody is human", (Claim 157).

C) "The antigen-binding fragment of claim 155 that is ... a monoclonal antibody designated AD5-4B8", (Claim 160)

D) "A kit comprising an antigen-binding fragment of claim 155 and a component selected from the group consisting of: BDCA-2 protein, a buffer, and a label conjugated to, or that can be conjugated to, the antigen-binding fragment", (Claim 179).

Applicant's amendment, filed 11/20/02, asserts that support for the new limitations can be found at various sites throughout the specification. In particular, the Table spanning pages 8 and 9 of the Remarks indicates specific sites supporting the limitations of each claim. However, support for the aforementioned specific limitations has not been found.

7. No claim is allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald

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Ewoldt whose telephone number is (703) 308-9805. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. **Please note:** any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 Customer Service Center at (703) 308-0198.



G.R. Ewoldt, Ph.D.
Primary Examiner
Technology Center 1600
October 20, 2003